K123734

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BD

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JAN 17 2013

510(k) Summary

21 CFR §807.92(c)

BD Nexiva™ Diffusics™ Closed IV Catheter System

Submitter Information	Submitter Name: Submitter Address:	Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, UT 84070
	Contact Person:	Kimberly Geisler Staff Regulatory Affairs Specialist kimberly_geisler@bd.com (801) 565-2422 (phone) (801) 565-2749 (fax)
	Date of Preparation:	December 4, 2012
Subject Device	Trade Name: Common Name: Classification Name: CFR Reference: Classification Panel:	BD Nexiva™ Diffusics™ Closed IV Catheter System Peripheral Intravascular Catheter or IV Catheter 80 FOZ - Intravascular Catheter 21 CFR 880.5200 – Class II General Hospital
Predicate Device	Trade Name: Common Name: Classification Name: CFR Reference: Classification Panel: Premarket Notification:	BD Nexiva™ Diffusics™ Closed IV Catheter System Peripheral Intravascular Catheter or IV Catheter 80 FOZ - Intravascular Catheter 21 CFR 880.5200 – Class II General Hospital K111366
Device Description	The BD Nexiva Diffusics device is designed to minimize blood exposure. It includes a passive needle-shielding mechanism designed to reduce accidental needlestick injury. The closed system is designed to keep blood contained within the device throughout the insertion process, which may prevent potential exposure for clinicians and patients. The system consists of a radiopaque Vialon® material catheter, a notched needle to enhance flashback visualization, a septum designed to remove visible blood from the needle surface that seals after needle removal, a stabilization platform, extension tubing, a clamp, a vent plug and a Luer connector. The 18-24 gauge catheter systems are capable of withstanding high pressure injection procedures. The stabilization platform and Luer adapter are color-coded.	

Indications for Use	The BD Nexiva™ Diffusics™ intravascular catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure or administer fluids. The BD Nexiva Diffusics catheters are suitable for use with power injectors when a direct connection is made.
Technological Characteristics	Technological characteristics of the subject BD Nexiva™ Diffusics™ Closed IV Catheter System are equivalent to that of the predicate BD Nexiva™ Diffusics™ Closed IV Catheter System with respect to device design and function. Differences include modifications to the maximum flow rate specifications. These differences do not raise any new questions regarding safety or effectiveness.
Summary of Safety and Performance Tests	Pursuant to 21 CFR §820.30, Design Controls, design verification and validation of the device modifications were performed according to the risk analysis in compliance with *ISO 14971:2009, Medical devices – Application of risk management to medical devices.* The following guidance documents and FDA recognized consensus standards, in conjunction with in-house protocols, were used to determine appropriate methods for evaluating the safety and performance of the device. ▪ *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995* ▪ *ISO 594-1:1986, Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain other Medical Equipment Part 1: General Requirements* ▪ *ISO 594-2:1998, Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain other Medical Equipment Part 2: Lock Fittings* ▪ *ISO 10555-1:1995 Amd2: 2004, Sterile, single use intravascular catheters- Part 1: General Requirements* ▪ *ISO 10555-5:1996 (E) Corrigendum 1, Am 1, Sterile, single use intravascular catheters- Part 5: Over-needle peripheral catheters* ▪ *ANSI/AAMI/ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* ▪ *FDA Blue Book Memorandum #G95-1, Use of International Standards ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* ▪ *ANSI/AAMI/ISO 10993-7:2008, Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals* ▪ *ANSI/AAMI/ISO 11135-1:2007, International Standard Sterilization of Health Care Products-Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices* ▪ *Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, August 30, 2002* ▪ *ANSI/AAMI/ISO 11607-1:2006, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems* ▪ *ANSI/AAMI/ISO 11607-2:2006, Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*

	Results of safety and performance testing demonstrated that the subject device met all predetermined acceptance criteria.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject BD Nexiva™ Diffusics™ Closed IV Catheter System meets the predetermined requirements under 21 CFR 820.30, Design Controls, and demonstrates that the subject device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 26, 2013

Ms. Kimberly Geisler
Staff Regulatory Affairs Specialist
Becton, Dickinson and Company
9450 South State Street
Sandy, UT 84070

Re: K123734
Trade/Device Name: BD Nexiva™ Diffusics™ Closed IV Catheter System
Regulation Number: 21CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: December 4, 2013
Received: December 5, 2013

Dear Ms. Geisler:

This letter corrects our substantially equivalent letter of January 17, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson -S
2013.03.26 16:12:54 -04'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123734

Device Proprietary Name: BD Nexiva™ Diffusics™ Closed IV Catheter System

Indications for Use:

The BD Nexiva™ Diffusics™ intravascular catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure or administer fluids. The BD Nexiva Diffusics catheters are suitable for use with power injectors when a direct connection is made. The maximum flow rate and maximum power injector pressure setting for each catheter size are listed in the table below:

	Max Flow Rate (mL/sec)	Max Injector Setting (psi)
24 GA x 0.75 IN	3.0	325
22 GA x 1.00 IN	6.5	325
20 GA x 1.00 IN	10.0	325
20 GA x 1.25 IN	10.0	325
18 GA x 1.25 IN	15.0	325

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Richard C. Chapman 2013.03.26 12:02:51 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____